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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,986	12/08/2003	Thomas Nilsson	246424US8	2822

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,986	NILSSON ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/8/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-43 are pending.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on application filed in Sweden on December 3, 2003. It is noted, however, that applicant has not filed a certified copy of the 0303269-5 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

The information disclosure statement (IDS) submitted March 8, 2004 is improper, because it is not on a 1449 form and is merely a listing of the instant application and copending applications by the same inventor. The Examiner respectfully suggests submitting a 1449 form, wherein the pre-grant publication number of copending applications 10/703,505, 10/603,819, and 10/729, 024 are provided.

Specification

The use of the trademarks SPIRIVA® (pg. 2, lines 28-29; pg. 3, lines 2 and 21; pg. 4, line 26; pg. 5, lines 6 and 30; pg. 6, lines 3, 13, 16, 23, and 29; pg. 7, lines 7, 17, and 28; pg. 8, lines 9, 15, and 22; pg. 9, lines 10, 18, Table 1, and line 25; pg. 11, lines 13, 15, 18, and 27; pg. 11, line 17; and pg. 14, line 4) and HANDIHALER® (pg. 2, line 29; pg. 6, lines 4, 16, 18, 23, and 29; pg. 7, lines 2, 7, 17, 22, and 28; pg. 8, lines 4, 9, 18, 22, and 28; pg. 9, lines 1, 7, 19, and Table 1; pg. 10, lines 11 and 16; pg. 14, line 10) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high" in claims 1, 5, 7, 12, 16-21, 23, 26, 28, 33, 38, and 39-42 is a relative term, which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is noted that the terms "high barrier seal" and "high barrier container" are defined on page 7 of the instant specification. Whereas these definitions appear to be adequate to define what a barrier seal and a barrier container are, they are insufficient to define the intended meaning of the word "high." These definitions utilize the relative term "high," and are therefore inherently indefinite. It would not be clear to a person of ordinary skill in the art what the term "high" is intended to mean, as it requires comparison with something else to ascertain what is intended. For example, it is unclear whether a high barrier to moisture is intended to mean that only a certain percentage

of moisture content, such as 1% moisture, may seep into the composition within a given time period.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-14, 16-24, 26-35, and 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies (US 2002/0053344).

The intended use of medical products and pharmaceutical compositions, steps involved in said intended use (e.g. administration), and the limitations of the vessel containing pharmaceutical compositions (claims 12-14, 16-22, 33-35, and 37-43) were given no weight in examination of the cited claims in the instant rejection.

Davies discloses an **inhalation device for use with a medicament pack** in which at least **one container for medicament in powder form** is defined between two sheets peelably secured to one another (title and abstract).

Davies discloses that the medicament pack comprises an elongate strip formed from a base sheet having a plurality of recesses spaced along its length and a lid sheet **hermetically but peelably sealed** thereto **to define a plurality of containers**, **each container having therein inhalable medicament in powder form** [0006].

Davies discloses in [0041] and Figures 1, 2, and 3a to 3c that the strip (1) comprises a base sheet (3) in which **blisters** are formed to define the **pockets** (2), and a lid sheet (4) which is **hermetically sealed to the base sheet (3)** except in the region of the blisters, such a manner that the lid sheet and the base sheet can be peeled apart. The **lid and base sheets are each**

preferably formed of a plastics/aluminum laminate, and the lid and base sheets are preferably adhered to one another by heat sealing. By way of example, the lid material may be a laminate consisting of 50 gsm bleach kraftpaper/12 micron **polyester** (PETP) film/20 micron **soft temper aluminum foil**/9 gsm vinylic peelable heat seal lacquer (sealable to PVC), and the base material may be a **laminate** consisting of 100 micron **PVC/45 micron soft temper aluminum foil/25 micron orientated polyamide**. The lacquer of the lid material is sealed to the PVC layer of the base material to provide the peelable seal between the lid and base sheets. Polyester, polyamides, and PVC are polymers. The seal is defined between two members, **peelably secured to one another** [0004].

Davies discloses in [0091] that the medicament dispenser of his invention is suitable to dispensing medicament **for the treatment of COPD and asthma**.

Davies discloses in [0092] that suitable medicaments include **ketotifen (anti-allergic), fluticasone (anti-inflammatory steroid), budesonide (anti-inflammatory steroid), rofleponide (anti-inflammatory steroid), mometasone (anti-inflammatory steroid), ciclesonide (anti-inflammatory steroid), ipratropium (anticholinergic), tiotropium (anticholinergic),** and where appropriate salts, esters, or solvates thereof.

Davies discloses in [0094] that suitable medicaments can also **be delivered in combinations**.

The hermetically sealed blister pack discloses by Davies is inherently constitutes a high barrier seal as part of a container.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 15, 25, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (US 2002/0053344) in view of Zierenberg, B. (WO 03/084502).

The intended use of pharmaceutical compositions as well as any steps involved in said intended use (e.g. administration) were given no weight in examination of the claims of the instant application.

The teachings of Davies have been set forth above.

Davies lacks the teaching of tiotropium-containing dry powder further comprising lactose.

Zierenberg teaches **inhalation kits** comprising **inhalable powder of tiotropium** and a **method for the administration of powdered preparations containing tiotropium via inhalation** (title and abstract).

Zierenberg teaches that **tiotropium** is a highly effective **anticholinergic** with a long lasting activity, which **can be used to treat respiratory complaints**, particularly **COPD** (chronic obstructive pulmonary disease) and **asthma** (pg. 1, lines 11-14).

Zierenberg teaches that another object of his invention provides for **an inhalation kit comprising a tiotropium containing powder and an inhalation device** (pg. 2, lines 12-13).

Zierenberg teaches that an inhalable powder of the active composition preferably comprises 0.12 to 0.48% tiotropium bromide in **admixture with a physiologically acceptable excipient** (pg. 3, lines 1-3). Examples of suitable excipients include, monosaccharides (e.g. glucose), **disaccharides (e.g. lactose)**, oligo- and polysaccharides (e.g. dextrane), polyalcohols (e.g. sorbitol), salts (e.g. sodium chloride) or mixtures thereof (pg. 3, lines 19-24).

Zierenberg teaches that **the average particle size of the suitable excipients** is preferably **between 10 to 500 microns**, wherein the term "average particle size" is understood to mean **mass median aerodynamic diameter (MMAD).** Excipients can optionally contain an added

fraction having a finer particle size, wherein the **average particle size is 1 to 9 microns** (pg. 3, lines 28-37).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Davies and Zierenberg, because both inventors teach inhalation devices for the delivery of dry powder compositions comprising tiotropium, which can be used in a method of treating COPD and asthma. It would have been apparent to a skilled artisan at the time of the instant invention that Davies' inhalation device, wherein the medicament dry powder is hermetically sealed, provides an obvious high barrier seal (i.e. it inhibits the ingress of moisture). A person of ordinary skill in the art at the time of the instant invention would have been motivated to combine the teachings of Davies and Zierenberg, because the hermetically sealed containers in Davies' device would increase the shelf life of the pharmaceutical compositions contained therein, because it would obviously prevent the ingress of air (i.e. oxygen) and moisture. Air and moisture often promote the degradation of active agents.

A skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because both prior art references teach inhalation devices containing dry powders comprising only tiotropium active agent or tiotropium in admixture with additional active agents and/or excipients, which may be used in the treatment of COPD and asthma. It would have been apparent to a skilled artisan at the time of the instant invention that Davies' device comprises a container a first part of which is adapted for insertion into a dry powder inhaler. It would have been further evident to a skilled artisan at the time of the instant invention that Davies' device obviously comprises a dry powder inhaler, because it is an inhalation device

suitable to deliver hermetically sealed powdered by inhalation administration of medicament for the treatment of COPD and asthma.

Regarding the amounts of excipients and active agents present in the compositions contained within the inhalation devices taught by the prior art, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Double Patenting

Applicant is advised that should claims 1, 12, 23, and 33 be found allowable, claims 11, 22, 32, and 43 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 11, 22, 32, and 43 recite an intended use of a medical product or pharmaceutical composition. The intended use of a medical product or pharmaceutical composition is given no weight. Therefore, claims 11, 22, 32, and 43 do not further limit the

independent claims from which they depend and are thus substantial duplicates of claims 1, 12, 23, and 33, respectively.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23-25 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 7, 8, 11-15, and 18-20 of copending Application No. 10/603,819 (copending '819). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. The claims of the instant application comprise tiotropium and at least one other active pharmaceutical agent chosen from several classes of drugs. The difference between claims 1, 2, 7, 8, 11-15, and 18-20 of copending '819 and claims 23-25 of the instant application is that the compositions of copending '819 are not drawn to specific drug classes. It is noted that the term "medicament" encompasses all drug

classes, and therefore all drugs. The method steps of copending '819 result in the synthesis of a medical product and pharmaceutical composition contained therein having limitations, which are obvious over the corresponding medical product and pharmaceutical composition recited in the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 23-25 and 33-36 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-17 and 19 of copending Application No. 10/703,505 (copending '505) in view of Akehurst (U.S. Patent No. 6,303,103) (USPN '103). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. The claims of the instant application comprise tiotropium and at least one other active pharmaceutical agent chosen from several classes of drugs, including inhalable steroids (e.g. fluticasone) and beta-agonists (e.g. formoterol). The difference between claims 12-17 and 19 of copending '505 and claims 23-25 and 33-36 of the instant application is that the compositions of copending '505 do not explicitly contain tiotropium.

The Examiner contends that the cited claims of the instant application are obvious over those of copending '505, because tiotropium is a known active agent and USPN '103 teaches that it is apparent to skilled artisans that aerosol formulations may contain a combination of two or more active ingredients (col. 3, lines 28-31). USPN '103 also teaches that aerosol compositions containing two active ingredients in a propellant system are known for the treatment of respiratory disorders (e.g. asthma) (col. 3, lines 30-31). USPN '103 teaches that the other

medicaments that can be included in aerosol formulations, includes the anticholinergic, ipratropium -a compound having the same core structure as tiotropium, also a known anticholinergic.

It would have been obvious to a person of ordinary skill in the art that one could substitute a compound with the same known activity for a different active ingredient (e.g. substituting ipratropium for tiotropium). In view of the teachings of Akehurst and the open language of the cited claims of the instant application, it would have also been apparent to a skilled artisan that the claims 12-17 and 19 of copending '505 are obvious over claims 23-25 and 33-36 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 12-14 and 16-22 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-12 of copending Application No. 10/729,024 (copending '024). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. No weight has been given to the limitations of the composition containers of the cited claims of the instant application, the intended use of a composition in either application in this comparative analysis. The claims of the instant application comprise tiotropium. The difference between claims 7-12 of copending '024 and claims 12-14 and 16-22 of the instant application is that the independent composition claim (i.e. claim 7) of copending '024 is generically drawn to a composition comprising an

anticholinergic. Subsequent dependent claims of copending '024 identify the anticholinergic as ipratropium bromide (claim 10 of copending '024), tiotropium bromide (claim 11 of copending '024), and oxitropium bromide (claim 12 of copending '024). Both ipratropium bromide and oxitropium bromide are anticholinergics that have similar chemical structures relative to the chemical structure of tiotropium.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-43 (all claims) are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8-16, 18, 22-23, 26, 28-42, 45, and 48 of copending Application No. 10/834,037 (copending '037) in view of Davies (US 2002/0053344).

The cited claims of the instant application and the claims of copending '037 are obvious over one another because both claim sets recite medical products comprising a dry powder dose of tiotropium loaded within a container comprising a high barrier seal that prevents the ingress of moisture. In the analysis of the two claim sets, no weight was given to procedural steps or the intended use of said medical products and the powder medicaments contained therein. The instant application does not disclose a specific excipient size; therefore any excipient size is suitable per what is generally known in the prior art regarding appropriate excipient particle size. Both claim sets also identify lactose as the excipient. Similarly, both claims sets identify that the barrier seal is made from aluminum foil laminated with polymers. Copending '037, however, does not recite that the container is a separate part adapted for insertion into a dry powder inhaler

(DPI). Davies et al. cures this deficiency through the teaching of an inhalation device, wherein the active powder medicament may be contained with in a peelable hermetically sealed blister pack comprising a plurality of dosages that can be inserted into a DPI (see the teachings of Davies set forth above). Davies also teaches that drug combinations may be used in the inhalation device, including combinations of tiotropium with steroids (e.g. budesonide), beta-agonists (e.g. salmeterol) etc. Therefore the cited claims of copending '037 and the instant application are *prima facie* obvious over one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented

Claims 23-25 and 33-36 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-20 of copending Application No. 10/870,909 (copending '909) in view of Akehurst (U.S. Patent No. 6,303,103) (USPN '103). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. The claims of the instant application comprise tiotropium and at least one other active pharmaceutical agent chosen from several classes of drugs, including inhalable steroids (e.g. budesonide) and beta-agonists (e.g. formoterol). The difference between claims 12-17 and 19 of copending '909 and claims 23-25 and 33-36 of the instant application is that the compositions of the instant application do not explicitly contain tiotropium.

The Examiner contends that the cited claims of the instant application are obvious over those of copending '909, because tiotropium is a known active agent and USPN '103 teaches that

it is apparent to skilled artisans that aerosol formulations may contain a combination of two or more active ingredients (col. 3, lines 28-31). USPN '103 also teaches that aerosol compositions containing two active ingredients in a propellant system are known for the treatment of respiratory disorders (e.g. asthma) (col. 3, lines 30-31). USPN '103 teaches that the other medicaments that can be included in aerosol formulations, includes the anticholinergic, ipratropium -a compound having the same core structure as tiotropium, also a known anticholinergic. Regarding the amounts of ingredients used, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

It would have been obvious to a person of ordinary skill in the art that one could substitute a compound with the same known activity for a different active ingredient (e.g. substituting ipratropium for tiotropium). In view of the teachings of Akehurst and the open language of the claims of the instant application, it would have also been apparent to a skilled artisan that claims 12-17 and 19 of copending '909 are obvious over claims 23-25 and 33-36 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-43 (all claims) are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35 (all claims) of copending Application No. 10/921,192 (copending '192).

The claims of the instant application and the claims of copending '192 are obvious over one another because both claim sets recite medical products comprising a dry powder dose of tiotropium loaded within a container comprising a high barrier seal that prevents the ingress of moisture. In the analysis of the two claim sets, no weight was given to procedural steps or the intended use of said medical products and the powder medicaments contained therein. The instant application does not disclose a specific excipient size; therefore any excipient size is suitable per what is generally known in the prior art regarding appropriate excipient particle size. Both claim sets also identify lactose as the excipient. Similarly, both claims sets identify that the barrier seal is made from aluminum foil laminated with polymers. Both applications recite in dependent claims that the container is a separate part adapted for insertion into a dry powder inhaler (DPI).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-11 and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 and 18 of copending Application No. 10/933,219 (copending '219) in view of Zierenberg (WO 03/084502). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. The

claims of the instant application are drawn to a medical product comprising a dry powder dose of tiotropium loaded into a container consisting of a dry high barrier seal, wherein the dry powder dose is adapted for administration by a dry powder inhaler. The claims of copending '219 are drawn to a pre-metered dry powder inhaler comprising a dry powder medicament dose and a container, wherein the container constitutes a dry high barrier seal. Both claim sets also recite limitations wherein in the dry powder dose comprises an excipient, including lactose (a disaccharide). The cited dependent claims also recite substantially similar limitations for the high dry barrier seal, such as being formed from a metallic material (e.g. aluminum). The term "medicament" used in copending '219 encompasses all known active agents, including tiotropium. One difference between claim sets is that copending '219 recites particles sizes of the excipient and the relative amount of said excipients. This deficiency is cured by the teachings of Zierenberg, set forth above, regarding the use of dry excipients (e.g. lactose) having an average particles size between 10 and 500 microns. Therefore, the cited claims of the instant application and copending '219 are prima facie obvious over one another.

This is a provisional obviousness-type double patenting rejection.

Other Matter

It is noted that there are currently two claims numbered 24. Appropriate correction is required.

Conclusion

The specification is objected. Claims 1-43 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER